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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,951

03/22/2005

Ian Flockhart

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,951	Applicant(s) FLOCKHART ET AL.	
	Examiner SAM P. SIEFKE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 1-97 and 100-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98 and 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-40,92-97, 100-103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group I-IV, VI and VII, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/6/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 1797

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straight, "Marihuana Exatraction and Purification for Oral Administration of Known Amounts of Delta 9-tetrahydrocannabinol (THC)." Biochemical Medicine 8, pg. 341-344 in view of 6,365,416.

Straight teaches a method of producing delta 9-tetrahydrocannabinol crystals that comprises the steps of i) obtaining an ethanolic solution of a botanical drug substance from cannabis plant material (pg. 342, lines 5-11), ii) passing the solution obtained in step i) through a column of activated charcoal (precolumn), and collecting the eluate, iii) remove solvent from the eluate by rotary evaporation to give a delta 9-tetrahydrocannabinol enriched fraction (pg. 342, lines 8-11), iv) passing a solution of the resulting delta 9-tetrahydrocannabinol enriched extract through a column packed with Sephadex LH20, eluting with chloroform/ethylacetate (pg. 342, lines 12-32), v) collecting delta 9-tetrahydrocannabinol rich fractions and removing solvent by rotary evaporation (pg 342, lines 20-26), vi) re-dissolving the crude delta 9-tetrahydrocannabinol prepared in step v) in methanol, removing insoluble residue by filtration and removing solvent from the filtrate by rotary evaporation (pg. 342, lines 26-28, concentrating and rechromatographed). Straight teaches the THCV produced is greater than 98% purity.

Straight does not teach a 2:1 chloroform/dichloromethane or re-dissolving in pentane to remove insoluble residue by filtration.

Elsohly teaches a method of preparing delta –tetrahydrocannabinol that comprises employing pentane as a non-polar solvent for extraction in column chromatography. It is well known in the art that solvent extraction employs pentane because it is a non-polar solution which employs different chemical interactions than polar solvents (ethanol extraction as employed in Straight). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to employ in addition to polar solvent extraction a non polar solvent extraction to remove impurities that are attracted to non polar solvents. This provides higher purity extraction process that is well known in the art.

Regarding the specific 2:1 chloroform/dichloromethane, it would have been obvious to one having an ordinary skill in the art to modify Straight to employ this specific elution fluid because through routine experimentation one would have looked from employing chloroform/ethylacetate to chloroform/dichloromethane because they have similar properties as elution fluids.

Regarding employing activated charcoal in the precolumn, it would have been obvious to one having an ordinary skill in the art to employ activated charcoal in a precolumn because activated charcoal is routinely employed for quick adsorption of impurities.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797